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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,768	03/26/2004	William F. Niland	HQS-107US	9079

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EXAMINER	
DEMILLE, DANTON D	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
10/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,768	NILAND ET AL.	
	Examiner	Art Unit	
	Danton DeMille	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18,20-39 and 42-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18,20-39 and 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 422. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the delivery tube, fitting and nasal cannula must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Claims 16-18, 20-39, 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims include a supply unit and a delivery tube assembly that appear to be elements 402 and 404 respectively as shown in figure 3. It has been assumed the claims are drawn to the embodiment of figure 3.

It is not clear if there is support in the original disclosure for the supply unit configured to deliver heated and humidified gas. As understood, the supply unit 402 delivers heated water through a heater 422, not shown, from a water bag 416. Humidified gas is provided through exchanger 410 from gas source 406. There appears to be no support for the supply unit to deliver "heated and humidified gas" or heats a breathing gas and combines the breathing gas with water vapor as claimed.

The delivery tube assembly is recited as having a delivery tube however, there appears to be no support in the original disclosure for the delivery tube.

The delivery tube assembly is recited as having a fitting however, there appears to be no support in the original disclosure for the fitting.

The delivery tube assembly is recited as configured to transfer heat to the heated and humidified gas received from the supply unit however, there appears to be no support in the original disclosure for this.

The system is recited as having a nasal cannula however, there appears to be no support in the original disclosure for the nasal cannula.

In claim 18 there appears to be no support in the original disclosure for the supply unit being configured to deliver humidified gas at a flow rate above about 20 liters per minute.

In claims 30, 31, 33 there appears to be no support in the original disclosure for a method for delivering heated and humidified gas to a neonatal patient. Additionally, there doesn't appear to be support for providing a water vapor content of at least about 40 milligrams per liter.

In claim 32 there appears to be no support in the original disclosure for delivering "only" heated and humidified gas through the cannula. The original disclosure would appear to comprehend the ability of the device to deliver gas that is not humidified by not allowing the passage of liquid water. There doesn't appear to be support for delivering "only" heated and humidified gas or why this is now critical or what is the novel feature of delivering "only" heated and humidified gas.

In claim 34 there appears to be no support in the original disclosure for fluid flowing "through and reverses direction in the delivery tube".

In claims 36, 39, 42 there appears to be no support in the original disclosure for the fluid flow to insulate the breathing gas prior to humidifying the breathing gas.

Applicant argues that they are entitled to incorporate this information by reference under 37 C.F.R. § 1.57 and that support for the missing items may be found in U.S. Patent App. Pub. No. 2003/0209246. While it may be true that the present application has support for such information, this application must still be amended to incorporate the missing information. As set forth under 37 C.F.R. § 1.57 (a)(1), "[t]he application must be amended to include the inadvertently omitted portion of the specification or drawing(s) within any time period set by the Office, but in no case later than the close of prosecution as defined by § 1.114(b), or abandonment of the application, whichever occurs earlier".

Claim Rejections - 35 USC § 103

Claims 30, 31, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graves (US 5,271,391) in view of Lammers (US 6,474,335).

Graves teaches a method for delivering humidified gas to a neonatal patient. The method comprises connecting a delivery tube 14 to a supply unit 12, coupling a nasal cannula 38 to the delivery tube, humidifying a breathing gas in a supply unit 5 by humidifier 18 and delivering the heated and humidified gas from the supply unit to the neonatal patient at a flow rate of about 4-8 litres per minute, column 4, line 55. Graves appears silent with regard to the exact water vapor content of the air. Such operational parameters are well within the realm of the artisan of ordinary skill in order to find the optimum operation dependent on practical considerations of intended use and the specific requirements of a specific patient.

Lammers teaches a heat and moisture exchanger in which "[a]ir to be inhaled preferably contains more than 30 mg H_2O per litre air", column 4, lines 46-47. Additionally Lammers teaches that the device can be used for new boar babies, column 4, line 50. The claimed 40 milligrams per litre would appear to be comprehended by Lammers. If it is felt that 40 milligrams is not greater than 30 milligrams it would be obvious to find the optimum operational parameters dependent on practical considerations of intended use and the needs of a particular patient. Lammers teaches that greater than 30 mg H_2O per litre air is preferable and 40 mg H_2O per litre air does not appear to be outside the realm of the artisan of ordinary skill. 40 does not appear to be that far of a stretch from "more than 30". It would have been obvious to one of ordinary skill in the art to modify Graves to use at least about 40 mg H_2O per litre air as suggested by Lammers to find the optimum parameters for a particularly critical patient.

Allowable Subject Matter

Claims 16-18, 20-29, 32, 34-39, 42-45 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action.

Response to Arguments

Applicant's arguments with respect to claims 30, 31, 33 have been considered but are moot in view of the new ground(s) of rejection.

Applicant has provided an affidavit from one of the inventors that argues that the ideal therapy for neonates is providing humidified air at 37°C with 90-95% relative humidity, or at least about 40 milligrams of water vapor per liter of air. However, Lammers teaches that humidified air to be inhaled by new born babies (neonates) preferably contains more than 30 milligrams water per liter of air which would appear to comprehend the claimed limitations. 40

mg water per liter of air is more than 30 as taught by Lammers. Therefore it would appear that Lammers suggests the same method claimed by applicant.

The affidavit also argues that there are no systems that provide humidified air up to 8 liters per minute through a nasal cannula. However, Graves teaches that therapy to an infant can include providing air at 4-8 liters per minute through a nasal cannula. While Graves doesn't appear to include humidified air, just the fact that up to 8 liters per minute of air through a nasal cannula can be administered to an infant would suggest the same results would be true for humidified air.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9 October 2009

/Danton DeMille/
Danton DeMille
Primary Examiner
Art Unit 3771